Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

Protocol summary

Study aim

The purpose of this study is to examine the effectiveness of cognitive behavioral therapy (CBT) on weight loss in obese and overweight adolescents

Design

The present study is a prospective randomized controlled trial (RCT) comparing the effect of CBT on weight reduction among overweight and obese Iranian adolescents.

Settings and conduct

The adolescents will be recruited from four outpatient pediatric clinics in Qazvin .

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 13–18 years, BMI ≥85th percentile for age and gender, and ability to attend CBT sessions. Exclusion criteria : adolescents with other causes of obesity such as Cushing Disease and hypoparathyroidism, being pregnant, having clinical mental health conditions or psychosis, taking specific medications that affected their weight (e.g. corticosteroids, anxiolytics), and participating in another weight loss RCT.

Intervention groups

CBT treatment sessions will be based on treatment strategies in the intervention group comprised six face-to-face sessions for adolescents and two sessions for their parents. In all sessions, nutritional recommendations and diet of the adolescents will be evaluated.

Main outcome variables

Primary outcomes will be changes in BMI, Child Dietary Self-Efficacy Scale (CDSS), Weight Efficacy Lifestyle questionnaire (WEL), Physical Exercise Self-Efficacy Scale (PES), Pediatric Quality of Life Inventory (PedsQL™ 4.0 Generic Core Scales), and self-reported physical activity and diet

General information

Reason for update

We had been registered this trial 6 years before prospectively. But it has recently changed unto a retrospective status. We received the following message from IRCT “ Please note that the existing validation errors in your trial is because this trial has been approved while the previous version of IRCT software was in use. Please check all the errors carefully and update accordingly. some of the major changes include reformatting protocol summary, entering inclusion and exclusion criteria in "one phrase for each criteria" format, providing a sharing plan, and adding more contact information.” Therefore, we have now updated recruiting time.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110530707N1**
Registration date: **2017-01-22, 1395/11/03**
Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**
Update count: **1**

Registration date

2017-01-22, 1395/11/03

Registrant information

Name
Seyedeh Fatemeh Miri
Name of organization / entity
Qazvin Medical Science University
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Investigator

Expected recruitment start date
2017-02-03, 1395/11/15
Expected recruitment end date
2017-06-15, 1396/03/25
Actual recruitment start date
2017-02-03, 1395/11/15
Actual recruitment end date
2017-08-12, 1396/05/21
Trial completion date
2018-03-06, 1396/12/15

Scientific title
Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents

Public title
Effectiveness of the Cognitive behavioral therapy(CBT) in improving nutritional and weight status in overweight adolescents
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age 13–18 years BMI ≥85th percentile for age and gender ability to attend CBT sessions
Exclusion criteria:
Cushing Disease hypoparathyroidism being pregnant having clinical mental health conditions or psychosis, taking specific medications that affected their weight participating in another weight loss RCT
Age
From **13 years** old to **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **110**
Actual sample size reached: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Each adolescent will be recruited at the pediatric clinic to which they referred for treatment. Randomization will be performed after checking eligibility criteria, signing of informed consent, and baseline assessment. An independent biostatistician will randomize the adolescents into two groups (CBT and TAU) using software program and stratifying with the pediatric clinics.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qazvin Medical Science University Ethics committee
Street address
Medical Science University, Shahid Bahonar Blvd
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2016-10-19, 1395/07/28
Ethics committee reference number
IR.QUMS.REC.1395.172

Health conditions studied

1

Description of health condition studied
overweight or obesity
ICD-10 code
E65, E66,
ICD-10 code description
Obesity and other hyperalimentation / Obesity due to excess calories

Primary outcomes

1

Description
weight
Timepoint
before intervention and after 6 month
Method of measurement
balance scale

Secondary outcomes

1

Description
body mass index
Timepoint
before and after intervention
Method of measurement
weigh(kg)/(height)2

2

Description
waist circumference
Timepoint
baseline and 6 month after intervention
Method of measurement
meter

3

Description
hip circumference
Timepoint
at baseline and 6 month after intervention
Method of measurement
meter

4

Description
energy intake
Timepoint
at baseline and 6 month after intervention
Method of measurement
food frequency questionnair

5

Description
physical activity
Timepoint
at baseline and 6 month after intervention
Method of measurement
physical activity questionnair

6

Description
health-related quality of life
Timepoint
at baseline and 6 month after intervention
Method of measurement
quality of life questionnaire

7

Description
self efficacy
Timepoint
at baseline and 6 month after intervention
Method of measurement
questionnaire

8

Description
body composition
Timepoint
at baseline and 6 month after intervention
Method of measurement
body analyser

Intervention groups

1

Description
Intervention group: Cognitive behavioral therapy (CBT) will be used in this study. Intervention group will receive CBT consisted of six weekly, face to face sessions.
Category
Behavior

2

Description
Control group: This group will not receive any treatment during the study.they will receive counseling sessions at the end of study similar to intervention group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
outpatient pediatric clinics
Full name of responsible person
Seyedeh Fatemeh Miri
Street address
Medical Science University, Shahid Bahonar Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Vice chancellor for research, Qazvin Medical Science University
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Medical Science University, Shahid Bahonar Blvd
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Email
Sdh@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin Medical Science University
Full name of responsible person
Seyedeh Fatemeh Miri
Position
MSc student
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact
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Qazvin University of Medical Sciences
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Amir H Pakpour
Position
PhD, Health education
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available

Data Dictionary	No - There is not a plan to make this available